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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,920	04/03/2001	Ronald G. Udell	33346/US/2	3656

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

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01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,920	UDELL ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in the application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2007 has been entered.

Examiner has acknowledged that claims 1-18 have been cancelled.

Claims 19-31 and newly added claims 32-45 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation of "the mixture." There is insufficient antecedent basis for the limitation in the claim.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 23-25, 27-31, 32, 36-38 and 40-45 are rejected under 35 U.S 103(a) as being unpatentable over Matsuyama (US 6485760) in view White (US 5431916) and Mcpeak (US 6303586).

Applicant claims an unitary soft gel capsule and/or a method of preparing a corosolic acid soft gel comprising rice bran oil and corosolic acid in a mixture in claimed amounts.

Matsuyama teaches an oral composition comprising corosolic acid for an increase in or lowering of blood sugar levels in a patient. Matsuyama teaches that corosolic acid can be encapsulated (see, column 5, lines 17) but does not specifically teach using a unitary soft gel capsule. Matsuyama also does not expressly teach including rice bran oil in the composition or the claimed amounts administered to a human.

White beneficially teaches (see, e.g. column 1 lines 17-41) that soft gelatin capsules containing pharmaceutical actives provide an excellent delivery of pharmaceutical actives because they are the preferred form for accurate and uniform delivery of pharmaceutical actives as well as they are convenient, portable and easy to swallow. The gel capsules can be seemless (i.e. unitary) and beneficially contain fillers to aid in producing an appealing final product. (see, e.g. column 6, lines 25-35 and column 9, lines 53-end)

Mcpeak et al. beneficially teach rice bran oil (i.e. the rice bran is in liquid form) to control blood glucose levels. (see, e.g., column 7 lines 52-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Matsuyama's oral composition teachings to include White's beneficial oral unitary soft gel teachings (e.g. it is beneficial to utilize a unitary soft gel capsule because they are the preferred form for accurate and uniform delivery of pharmaceutical actives as well as they are convenient, portable and easy to swallow and also to benefically include fillers with an unitary gel capsule to produce an appealing final product) and also to include the beneficial teachings as taught by Mcpeak's active ingredient which is being utilized for the maintaining or lowering of blood glucose levels in humans to obtain the claimed unitary soft gel capsule composition and/or to prepare a corosolic acid soft gel for the oral administration of corosolic acid and rice bran oil in a unitary soft gel capsule for the maintaining or lowering blood sugar levels in humans. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which

is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose". Furthermore, the adjustment of other conventional working conditions (e.g. the amount of corosolic acid contained within the unitary soft gel capsule, heating the rice brain oil and placing the claimed active ingredients within a vacuum), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please Note that patentabililty of a product (i.e. the claimed unitary soft gel capsule) does not depend upon it method of production (i.e. corosolic acid alcohol extracted from *Lagerstroemia Speciosa L.*). If the product in the product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Claims 20-22 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuyama (US 6485760) in view of White (US 5431916), Mcpeak (US 6303586) as applied to claims 19, 23-25 and 27-31 above and further in view of Walter (US 368088), Dickinson (US 3665009) and LaGrone (US 6407068).

Applicant claims an unitary soft gel capsule capsule and/or a method of preparing a corosolic acid soft gel comprising rice bran oil, corosolic acid, the filler yellow bee's wax and silica in a mixture of claimed amounts.

In further view of the combined reference of Matsuyama, White and Mcpeak that teach an improved claimed composition comprising corosolic and rice bran oil contained within an unitary soft gel capsule for maintaining of lowering blood sugar levels in humans. The combined references, however, do not that the inclusion of silica and the filler yellow bee's wax in a mixture of the claimed amounts contained within the claimed unitary soft gel composition.

Both Walter (see, e.g. example 3) and Dickinson (see, e.g. column 5 line 57 and column 6 lines 1-9) teach it is beneficial to prepare soft gel capsules to aid in oral administration by filling the soft gel capsules with yellow bee's wax and/or bee's wax.

LaGrone beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes. (see, e.g., column 4 lines 11-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Matsuyama's oral composition teachings to include White's beneficial oral unitary soft gel teachings (e.g. it is beneficial to utilize an unitary soft gel capsule because they are the preferred form for accurate and uniform delivery of pharmaceutical actives as well as they are convenient, portable and easy to swallow) (and also please note: the yellow bees wax as taught by both Walter and Dickinson can be utilized as a filler within the claimed unitary soft gel capsule to aid in oral

administration of the unitary soft gel capsule) and also to include other beneficial teachings taught by Mcpeak and LaGrone whereas Mcpeak and LaGrone's active ingredients are each being utilized for the maintaining or lowering of blood glucose levels in humans to obtain the claimed unitary soft gel capsule composition and/or to prepare a corosolic acid soft gel for the oral administration of corosolic acid, rice bran oil, silica and yellow bee's wax in an unitary soft gel capsule for the maintaining or lowering blood sugar levels in humans. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose". Furthermore, the adjustment of other conventional working conditions (e.g. the amount of corosolic acid contained within the soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 26 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuyama (US 6485760) in view of White (US 5431916), Mcpeak (US 6303586), Walter (US 368088), Dickinson (US 3665009) and LaGrone (US 6407068) as applied to claims 19-25 and 27-30 in further view of Shanmuyasundam et al. (US 5980902).

Applicant claims an unitary soft gel capsule capsule and/or a method of preparing a corosolic acid soft gel comprising rice bran oil, corosolic acid, the filler yellow bee's wax, silica and an extract of *Gymnema sylvestre* in a mixture of claimed amounts.

In further view of the combined reference of Matsuyama, White, Mcpeak, Walter, Dickinson and LaGrone that teach an improved claimed composition comprising corosolic acid, rice bran oil, the filler yellow bee's wax and silica contained within an unitary soft gel capsule for maintaining of lowering blood sugar levels in humans. The combined references, however, do not that the inclusion of an extract of *Gymnema sylvestre* in a mixture of the claimed amounts contained within the claimed unitary soft gel composition.

Shanmyasundam et al. benefically teach an extract of *Gymnema sylvestre* for controlling blood sugar to prevent obesity. (see, e.g. column 3 lines 16-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Matsuyama's oral composition teachings to include White's beneficial oral unitary soft gel teachings (e.g. it is beneficial to utilize an unitary soft gel capsule because they are the preferred form for accurate and uniform delivery of pharmaceutical actives as well as they are convenient, portable and easy to swallow) (and also please note: the yellow bees wax as taught by both Walter and Dickinson can be utilized as a filler within the claimed unitary soft gel capsule to aid in oral administration of the unitary soft gel capsule) and also to include other beneficial teachings taught by Mcpeak, LaGrone and Shanmyasundam whereas Mcpeak,

LaGrone and Shanmyasundam's active ingredients are each being utilized for the maintaining or lowering of blood glucose levels in humans to obtain the claimed unitary soft gel capsule composition and/or to prepare a corosolic acid soft gel for the oral administration of corosolic acid, rice bran oil, silica yellow bee's wax and an extract of *Gymnema sylvestre* in an unitary soft gel capsule for the maintaining or lowering blood sugar levels in humans. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose". Furthermore, the adjustment of other conventional working conditions (e.g. the amount of corosolic acid contained within the soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE
PRIMARY EXAMINER